Remarks

In the outstanding Official Action, the Examiner:

(1) rejected claims 1-4 under 35 USC 103(a) as being unpatentable over Cardon et al. in view of Kleshinski;

(2) rejected claim 5 under 35 USC 103(a) as being unpatentable over Cardon et al. in view of Kleshinski as applied to claim 4 above, and further in view of Solem et al.; and

(3) rejected claim 12 under 35 USC 103(a) as being unpatentable over Solem et al. in view of Kleshinski.

In response to Item 1 above, Applicants have now amended independent claim 1 to more clearly distinguish the present invention from the prior art of record.

Claim 1 comprises apparatus for reducing mitral regurgitation, the apparatus comprising a distal end section having a first fixed length in a direction parallel to the longitudinal axis, and a plurality of proximally-extending barbs disposed within the first fixed length of the distal end section, a proximal end section having a second fixed length in a direction parallel to the longitudinal axis, and a plurality of distally-extending barbs disposed within the second fixed length of the proximal end section, and at least one spring segment configured in an extended state to provide a first given length between the distal end section and the proximal end section in the first configuration and configured in a contracted state to provide a second given length between the distal end section and the proximal end section in the second configuration, and the second given length being shorter than the first given length, wherein the elongated body is adjusted from the first configuration to the second configuration so as to urge the

distal end section and the proximal end section toward one another, whereby when the elongated body is inserted into the coronary sinus in the first configuration, the at least one spring segment adjusts the elongated body to assume the second configuration so as to exert the force on the posterior annulus and thereby reduce mitral regurgitation.

Applicants believe that Cardon et al. disclose a stent having an axially flexible cylindrical part between two axially rigid cylindrical parts, and the axially flexible cylindrical part is a meshing of wires of cylindrical section. In addition, Applicants believe that Cardon et al. disclose that the "different flexible and rigid parts of the said stents, which are radially expandable, are in fact expanded in situ - inside a blood vessel or any other part of the human body - under the action of an expandable balloon." (See column 4, lines 44-48.) Applicants believe that this radial expansion of the axially flexible part changes the angle of the mesh components relative to the longitudinal axis of the axially rigid cylindrical parts, and that this expansion of the mesh components reduces the axial length of the flexible cylindrical part.

Applicants believe that Kleshinski discloses an anastomosis device having a skeletal frame of spring metal, plastic or similar material designed to expand from a collapsed configuration within a delivery catheter to an expanded configuration within two body vessels so as to hold the anastomosis device in place and create an effective fluid seal with the luminal walls of the two body vessels.

Applicants believe that neither Cardon et al. nor Kleshinski either alone or in combination with one another teach or suggest apparatus for reducing mitral regurgitation having at least one

spring segment configured in an extended state to provide a first given length between the distal end section and the proximal end section in the first configuration and configured in a contracted state to provide a second given length between the distal end section and the proximal end section in the second configuration, and the second length being shorter than the first given length. Applicants believe that Cardon et al. teach away from the present invention as claimed inasmuch as the stent does not include a spring element and the mesh portion of the axially flexible cylindrical part is expanded rather than contracted to reduce the axial length thereof. Applicants believe that Kleshinski teaches away from the present invention inasmuch as the skeletal frame expands rather than contracts after placement to hold the anastomosis device in place. Accordingly, Applicants believe that claim 1 is in condition for allowance, and allowance thereof is respectfully requested.

Claims 2-4, which depend either directly or ultimately from independent claim 1, are believed to be in condition for allowance for at least the above-identified reasons. Accordingly, allowance of claims 2-4 is respectfully requested.

In response to Item 2 above, Applicants have now amended independent claim 1 to more clearly define the present invention from the prior art as discussed hereinabove.

Applicants believe that Solem et al. disclose a method for the treatment of mitral annulus dilation using a device with an elongate body having two states, which include a stretched or extended state and a contracted state. Applicants believe that Solem et al. disclose an elongate body of one, two or more strings of memory metal that extend from the proximal end to the distal end of the device. Applicants believe that the disclosure

by Solem et al. of memory metal strings extending the length of the device teach away from the present invention as claimed in which the distal end section and the proximal end section are each configured with a fixed length and at least one spring segment is configured to adjust the length therebetween. Applicants believe that neither Cardon et al., Kleshinski, nor Solem et al. teach or suggest apparatus for reducing mitral regurgitation having a distal end section having a first fixed length in a direction parallel to the longitudinal axis, and a plurality of proximally-extending barbs disposed within the first fixed length of the distal end section, a proximal end section having a second fixed length in a direction parallel to the longitudinal axis, and a plurality of distally-extending barbs disposed within the second fixed length of the proximal end section, and at least one spring segment configured in an extended state to provide a first given length between the distal end section and the proximal end section in the first configuration and configured in a contracted state to provide a second given length between the distal end section and the proximal end section in the second configuration, and the second length being shorter than the first given length. Accordingly, claim 5, which depends ultimately from independent claim 1 is believed to be in condition for allowance for at least the above-identified reasons.

In response to Item 3 above, Applicants have now amended claim 12 to more clearly distinguish the present invention from the prior art of record.

Claim 12 comprises a method for reducing mitral regurgitation, the method comprising the steps of providing a prosthesis comprising a distal end section having a first fixed

length in a direction parallel to the longitudinal axis, and a plurality of proximally-extending barbs disposed within the first fixed length of the distal end section, a proximal end section having a second fixed length in a direction parallel to the longitudinal axis, and a plurality of distally-extending barbs disposed within the second fixed length of the proximal end section, and at least one spring segment configured in an extended state to provide a first given length between the distal end section and the proximal end section in the first configuration and configured in a contracted state to provide a second given length between the distal end section and the proximal end section in the second configuration, and the second given length being shorter than the first given length, wherein the elongated body is adjusted from the first configuration to the second configuration so as to urge the distal end section and the proximal end section toward one another, whereby when the elongated body is inserted into the coronary sinus in the first configuration, the at least one spring segment adjusts the elongated body to assume the second configuration so as to exert the force on the posterior annulus and thereby reduce mitral regurgitation; positioning the prosthesis in the coronary sinus while in the first configuration; and reconfiguring the prosthesis into the second configuration.

Applicants believe that Kleshinski discloses a method for forming a graft between two body vessels with an anastomosis device having a skeletal frame of spring metal, plastic or similar material designed to expand from a collapsed configuration within a delivery catheter to an expanded configuration within the two body vessels so as to hold the

anastomosis device in place and create an effective fluid seal with the luminal walls of the two body vessels.

Applicants believe that Solem et al. disclose a method for the treatment of mitral annulus dilation using a device with an elongate body having two states, which include a stretched or extended state and a contracted state. Applicants believe that Solem et al. disclose an elongate body of one, two or more strings of memory metal that extend from the proximal end to the distal end of the device.

Applicants believe that neither Kleshinski nor Solem et al. either alone or in combination with one another teach or suggest a method for reducing mitral regurgitation comprising apparatus for reducing mitral regurgitation having a distal end section having a first fixed length in a direction parallel to the longitudinal axis, and a plurality of proximally-extending barbs disposed within the first fixed length of the distal end section, a proximal end section having a second fixed length in a direction parallel to the longitudinal axis, and a plurality of distally-extending barbs disposed within the second fixed length of the proximal end section, and at least one spring segment configured in an extended state to provide a first given length between the distal end section and the proximal end section in the first configuration and configured in a contracted state to provide a second given length between the distal end section and the proximal end section in the second configuration, and the second length being shorter than the first given length. Applicants believe that Kleshinski teaches away from the present invention inasmuch as Kleshinski discloses a method for forming a graft between two body vessels, and the skeletal frame expands rather than contracts after placement to hold the anastomosis

device in place. Applicants believe that Solem et al. teach away from the present invention as claimed inasmuch as Solem et al. disclose an elongate body of memory metal that extends from the proximal end to the distal end of the device with the barbs disposed thereon rather than a distal end section and a proximal end section of a fixed length and at least one spring segment configured to adjust the length therebetween. Accordingly, Applicants believe that claim 12 is in condition for allowance, and allowance thereof is respectfully requested.

In the event that any additional fees may be required in this matter, please charge the same to Deposit Account No. 16-0221.

Respectfully submitted,

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